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LOW-LEVEL LASER THERAPY: A NEW TREATMENT ALTERNATIVE EFFECTIVE FOR ACUTE EXERCISE-RELATED TENDINITIS

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Low-Level Laser Therapy: A New Treatment Alternative

Effective for Acute Exercise-Related Tendinitis

INTRODUCTION

Musculoskeletal injuries and disorders are a leading health problem and economic burden for both the American public and the US Armed Forces. They limit the activity of more Americans than any other disease category[1] with 9% to 10% of the American population experiencing an acute musculoskeletal injury each year.[1] Occupationally related musculoskeletal injuries are associated with an estimated annual economic cost of $13 to $20 billion.[2] Musculoskeletal injuries are the most common adverse effect of regular exercise, with reported injury rates as high as 65% in recreational runners.[3,4] In the US Armed Forces, musculoskeletal injuries are a major cause of medical attrition, lost training efficiency, and reduced operational readiness with injuries among trainees occurring at rates of 20% to 60%[5-8] and resulting in lost training days 5 to 10 times that due to illness.[7] The annual cost of injury-related disabilities in the US military forces exceeds $750 million, with musculoskeletal injuries the leading disability diagnoses for the Marine Corps, Navy, and Army.[7]

Current treatment options for musculoskeletal injuries are limited. The mainstays of conservative therapy are nonsteroidal anti-inflammatory drugs (NSAIDs) in conjunction with therapeutic modalities that use electromagnetic, infrared, or acoustic energy transfer. NSAIDs can be associated with high costs and adverse side effects, and they are frequently ineffective, particularly if used in the absence of rehabilitation.[9-11] The therapeutic modalities currently applied for musculoskeletal injury treatment are often time-consuming, expensive, and without

scientific evidence demonstrating their effectiveness.[9-12] For many musculoskeletal injuries, failed conservative medical therapy leads to costly surgical interventions.

The Food and Drug Administration has recently cleared a new technology, low-level laser therapy (LLLT), for therapeutic use in the management of musculoskeletal injuries and disorders. Specific indications cleared by the FDA include hand and wrist pain associated with carpal tunnel syndrome; chronic neck and shoulder pain associated with osteoarthritis, muscle spasm, and cervical/thoracic spine sprains/strains; and minor muscle and joint pain associated with arthritis and muscle spasm. LLLT devices are noninvasive and have no known adverse effects. Their therapeutic effects in musculoskeletal tissue are believed to occur through reductions in inflammation and through stimulation of collagen synthesis.[13-18] Laboratory studies suggest that these physiological processes are initiated at the cellular level through the photochemical conversion of absorbed laser light energy into usable metabolic energy. Low-level laser irradiation of cells has been shown to result in production of adenosine triphosphate (ATP), in changes in intracellular pH, and in wavelength-dependent modifications of a number of cellular metabolic processes.[19] Research supports the theory that the conversion of laser energy to ATP occurs through the photoexcitation of mitochondrial photoacceptor molecules (which absorb the laser energy) and the resultant alterations in mitochondrial redox properties and accelerated electron transport.[19]

Although new to the United States, LLLT has been used in other countries for decades, and a number of clinical trials have demonstrated its efficacy in the management of a variety of musculoskeletal injuries and disorders.[17, 20-27] However, almost all studies have included

primarily chronic conditions and injuries of long duration.[17] Few studies have investigated the effects of LLLT on acute musculoskeletal injuries, and none have studied LLLT as an adjunct to conservative medical therapy for musculoskeletal injuries.

The study presented here was the first clinical trial to investigate the efficacy of LLLT as an adjunct to conservative medical therapy in the treatment of an acute exercise-induced musculoskeletal injury. The purpose of this randomized, double-blinded, placebo-controlled trial was to determine if LLLT in conjunction with conservative medical therapy would result in a more rapid reduction in the pain and functional disability associated with acute iliotibial band syndrome (ITBS) than conservative medical therapy alone. ITBS, one of the most common exercise-related repetitive stress injuries in both military[5,6,28] and civilian[29] populations, is an inflammation of the iliotibial band tendon, usually where it crosses the knee, caused by activities that require repeated knee flexion-extension such as running and cycling. The study hypothesis was that LLLT would promote an early accelerated reduction in ITBS pain and disability during the first six days of treatment, the inflammatory phase of tendon healing,[9,30] by reducing iliotibial band inflammation. After the early LLLT-enhanced reduction in ITBS pain and disability, symptoms in the nonlaser group were expected to decrease to the level of those of the LLLT group as a result of natural healing and medical therapy. Secondary research objectives were to (a) determine if LLLT, used in conjunction with conservative medical therapy, would reduce pain medication requirements for the treatment of acute ITBS; and (b) determine if LLLT with conservative medical therapy was more efficacious than conservative medical therapy alone in returning patients with acute ITBS to full normal activity, including vigorous exercise. The study was conducted at the Marine Corps Recruit Depot (MCRD) San Diego. United States Marine Corps (USMC) recruits were an ideal study population because of their high incidence of ITBS,

the diversity of the population, and the regimented training and living environments that provided control over many potential study confounders.

METHODS

Clinical Study Design

The study was a double-blinded, randomized, placebo-controlled clinical trial, conducted at the MCRD San Diego Medical Clinic from September 1999 to July 2000. Participants were healthy male, active-duty USMC recruits with new onset acute ITBS. Recruits were randomly assigned to either an active laser plus conservative medical therapy group (LLLT group) or to a placebo (sham) laser plus conservative medical therapy group (Placebo group). Conservative medical therapy consisted of a standardized regimen of naproxen, ice, stretching exercises, and relative rest. Recruits received a total of 6 active or sham LLLT treatments, 3 per week for 2 weeks, administered by trained laser technicians. Treatment efficacy was assessed immediately prior to each LLLT session and at the completion of all 6 LLLT sessions (trial day 14) using validated self-report questionnaires. LLLT effect durability was measured post treatment, at approximately weekly intervals for 4 weeks, using a self-report questionnaire. Study participants, laser technicians, and referring clinicians were blinded to participant group assignment throughout the trial.

Participants

Participants consisted of 55 healthy male active-duty USMC recruits with ITBS, ages 17 to 26 years, who voluntarily presented to the clinic within 2 weeks of onset of symptoms and with a minimum subjective pain level of 3 points on a 10-point visual analogue scale (VAS). The study sample was all male since only male recruits are trained at MCRD San Diego. Recruits with ITBS were first evaluated and diagnosed by physicians or physicians' assistants and then

referred to trained laser technicians for study inclusion/exclusion criteria screening. Recruits who successfully completed the screening and volunteered to participate then signed an informed consent form approved by the Committee for the Protection of Human Subjects of the Naval Health Research Center, San Diego, and administered by the laser technicians.

Recruits were excluded from study participation if they had (a) other musculoskeletal injuries that required medications or that limited exercise/training; (b) abnormal findings on knee exam not included in the ITBS case definition; (c) a history of prior knee surgery, intra-articular derangement, arthritis, or knee locking or giving way; (d) contraindications to NSAIDs; (e) a history of any chronic diseases, including skin cancers; (f) a history of substance abuse or psychological instability; or (g) prior medical treatment for their ITBS.

ITBS Case Definition.

Cases of ITBS were diagnosed by history and physical examination as is current clinical practice.[9,28,31,32] A standardized set of diagnostic criteria was established prior to the conduct of the study by a consensus meeting of local sports medicine professionals and was based on current ITBS clinical guidelines.[9,10,28,31,32] Prior to enrollment in the study, each participant underwent a medical history and full physical examination of the knee. Subjective diagnostic criteria for acute ITBS included a history of insidious onset within the previous 2 weeks of localized lateral knee pain precipitated and aggravated by physical activities involving repetitive knee flexion-extension. Objective criteria included findings on physical examination of a focal point of maximal tenderness over the distal iliotibial band where it crosses the lateral femoral

condyle, full knee joint range of motion, and at least one positive ITBS provocative test. Provocative tests included the Noble's compression test[33] and Garrick's test for ITBS.[32]

LLLT Device Characteristics

The ACCULASER Pro®, a low-energy gallium-aluminum-arsenide infrared diode laser, was used in this trial. It consists of four laser diodes; each emits a continuous wavelength of 830 nanometers, a power density of 310 mW per cm^2 at the skin surface, and an output power of 30±3 mW (total nominal output power 120 mW ± 10%). The laser light is invisible and emits no heat or other physically detectable effects when activated. The physical appearance and operating procedures of the sham laser were identical to those of the active laser; however, the sham laser contained no laser diodes. The laser devices were regularly tested and calibrated throughout the conduct of the study to insure consistent operating parameters.

Treatment Intervention

At study enrollment, recruits were randomly assigned to the LLLT or the Placebo group using a random numbers table. Trained laser technicians enrolled study participants and assigned them to treatment groups. Treatment procedures were identical for both groups. Recruits received a total of 6 LLLT treatments (active or sham), 3 per week on nonconsecutive days for 2 weeks. LLLT treatments were delivered by laser technicians with the recruit in the supine position, the treated knee in 30 degrees of flexion, and the LLLT device placed in direct contact with the skin. Six joules of laser energy, a dose of 15 joules per cm^2 per laser diode, were delivered at each of 5 anatomic sites along the distal portion of the iliotibial band: the point of maximal tenderness over

the femoral epicondyle, two successive points immediately proximal to and one point immediately distal to the point of maximal tenderness, and over Gerdy's tubercle.

Both groups also received conservative medical therapy consisting of (a) naproxen, 500 mg every 12 hours for 10 days; (b) ice over the distal ITB twice daily until symptoms resolved; (c) 3 ITB stretching exercises (standing stretch, seated stretch, gluteus stretch), performed twice daily until symptoms resolved; and (d) relative rest as clinically indicated, including reduced physical training, knee immobilizer, and/or crutches. Additional courses of naproxen were prescribed at the clinician's discretion for recruits with persistent ITBS symptoms.

Treatment Efficacy Assessment

The study hypothesis was that the LLLT group would experience during the first treatment week an initial accelerated reduction in ITBS symptoms relative to the Placebo group, after which differences between the groups would disappear as a result of natural healing and the medical therapy. However, since the exact timing of the anticipated pattern of response was not known, efficacy measurements were taken immediately prior to each of the 6 LLLT sessions, and at day 14 of study participation. To control for the natural healing process, all participants' fourth measurement session took place on day 7 of study participation, after 3 LLLT sessions, and their final efficacy measurements on day 14 of study participation, after all 6 LLLT sessions.

LLLT treatment efficacy was assessed using self-report questionnaires that measured changes in the participants' ITBS pain and functional disability. Questionnaire items included

three scales for measuring knee pain and function: a Knee VAS Questionnaire (KVQ), a Clinical Injury Severity Grade (CISG), and a Symptom Improvement Category Rating (SICR).

The KVQ consisted of twenty-two, 10-point VASs and was based on a previously validated questionnaire developed by the Hughston Orthopaedic Clinic for clinical and research evaluation of knee musculoskeletal disorders.[34-36] The 22 questions were categorized into 3 subscales: (a) pain and stiffness, (b) disability during sports and physical training (such as running, marching, jumping), and (c) disability during activities of daily living (such as walking, climbing stairs). A KVQ Score was calculated from participant responses using methods previously described.[34,35] Each VAS response was assigned a numerical value ranging from 1 (no symptoms) to 10 (maximum symptoms). The sum of the 22 responses was divided by the maximum possible (220) and multiplied by 100 to give a KVQ Score ranging from 10 to 100.[34,35] Missing and "not attempted" responses were assigned the average value of answered items within the same subscale.

The CISG was a six-level categorization system widely used by clinicians to rate the severity of musculoskeletal injuries (grade 1 = no pain or disability, grade 6 = pain during daily activities).[9,10,37] For the SICR, the participant rated his overall ITBS knee symptoms compared to symptoms at his previous treatment session, with possible responses being 1 = worse, 2 = no change, 3 = better, 4 = much better, and 5 = resolved (no pain).

Questionnaires also assessed participant demographics, history of ITBS symptoms, medical therapy compliance, and potential confounders to treatment effect. At each LLLT session, recruits rated their compliance with each component of the medical therapy regimen

using 10-point VASs (never, 1; always, 10). To assess overall medical therapy compliance, a Compliance Score was calculated from the VAS responses using a procedure similar to that used for the KVQ Score. To assess compliance with individual components of medical therapy (naproxen use, icing, stretching, light duty), the corresponding VAS responses were collapsed into two categories: "high compliance" (responses 8, 9, and 10) and "not high compliance" (responses 1 through 7).

Medication requirements for ITBS, defined as reported number of days of some medication use, and days of ITBS disability, defined as reported number of full or partial days of reduced training duty, were assessed at each treatment session by recruit interviews by laser technicians. Reduced training was prescribed by physicians or physicians' assistants and ranged from modified training (no high-impact exercise) to training cessation and referral to the Medical Rehabilitation Platoon (MRP).

Treatment effect durability was measured posttreatment approximately weekly for 4 weeks using self-report questionnaires and the SICR scale. Recruits with partial or full recoveries on day 14 who reported worsening of symptoms (SICR response 1) at any follow-up session were considered to have a nondurable treatment effect; all other SICR responses were considered a durable effect. A partial recovery was defined as a KVQ Score of 30 or less, a CISG of 2 (mild symptoms) or less, and full-duty status for at least the 2 preceding days. Full recovery was defined as a KVQ Score of 23 or less (based on Hoher et al., 1995), a CISG of 1 (no symptoms), and full-duty status for at least the 2 preceding days.

Recruit questionnaire responses were confirmed by medical and administrative records review, when available, including individual patient records, pharmacy records, physical therapy records, USMC training platoon rosters, MRP rosters, and recruit medical separation records.

Validity of Treatment Efficacy Measurements

Multiple statistical correlations and comparisons were performed using study data to examine the reliability and validity of the three efficacy measures (the KVQ Score, CISG, and SICR) for USMC recruits. All three measures were found to be highly reliable and valid for both injured and healthy recruits.[38] Cronbach's alpha and the average inter-item correlations were determined for the KVQ Score at baseline, when ITBS symptoms were most severe, and at day 14, when symptoms were least, to evaluate reliability of the total KVQ Score and of each subscale. The KVQ showed high reliability estimates for the total score and subscales at both time periods, with average inter-item correlations ranging from 0.42 to 0.88, and all Cronbach alpha coefficients exceeding 0.89, except for the baseline pain and stiffness scale (alpha = 0.796). Pearson's product-moment correlations showed moderate to high correlations between the KVQ Score, CISG, and the SICR at successive measurement sessions, demonstrating overlap between measures. Comparisons of mean KVQ Scores, CISG, and SICR over time, using *t* tests for paired measures, for a subset of healthy recruits (those who returned to full training duty and stayed there) and a subset of injured recruits (those who did not return to full duty) provided evidence of the reliability and validity of the three measures for both healthy and injured recruits. For the healthy recruits, mean KVQ Score, CISG, and SICR significantly improved over time and then stabilized in the mild to resolved symptom range; for the injured recruits, means showed no significant change over time, remaining in the moderate to severe symptom range.

Finally *t*-test comparisons of group means between the cohort of healthy recruits and the cohort of injured recruits showed that the KVQ Score, CISG, and SICR were consistently significantly poorer for the injured recruits, and the differences between the groups became more extreme with time. On day 14, the mean KVQ Score was 6.4 standard deviations worse for the injured recruits, the CISG 3.6 standard deviations, and the SICR 1.4 standard deviations.

Efficacy Endpoints

The primary efficacy endpoints were the mean KVQ Score and the mean SICR.

Group differences in mean KVQ Score and mean SICR were examined at each treatment session. A difference of 0.5 points in mean SICR and 6 points in mean KVQ Score (based on Hoher et al.'s validation study of the Hughston Clinic knee questionnaire) were considered clinically meaningful.[35] Additional clinical endpoints included the proportion of recruits in each group with (a) 30% or greater reduction from baseline in KVQ Score, (b) 50% or greater reduction from baseline in KVQ Score, (c) some symptom improvement since previous treatment session (SICR responses 3, 4, or 5) versus none (SICR responses 1 or 2), and (d) reported symptoms resolved (CISG 1) versus not resolved (CISG 2-6). The KVQ Score and SICR proportions were compared at each treatment session; the CISG at the end of the first and the end of the second treatment week. A group difference of 10% in these additional clinical measures was considered clinically meaningful.

Secondary efficacy endpoints were mean medication days and mean ITBS disability days. Group differences were examined for three time periods: during the 2-week treatment phase, during the follow-up phase, and for the entire study period, with a difference of 1 day

considered clinically significant. The treatment effect durability endpoints were the percentage of recruits with partial and full recoveries who had a durable effect. Successful durability for the LLLT group was defined as equivalent or better durability than for the Placebo group.

Safety Outcomes

Adverse events were not expected since the ACCULASER Pro® is a nonsignificant risk medical device.[39] However, at each LLLT session, laser technicians queried recruits regarding adverse events, and all complaints and adverse events were reported in narrative summary.

Statistical Analysis

Group differences in mean KVQ Score and mean SICR were examined by analysis of variance with covariates for treatment group effect. For the mean KVQ score, covariates included baseline KVQ Score and Compliance Score; for mean SICR, Compliance Score. Group mean medication days and mean ITBS disability days were compared using *t* tests. Group differences in categorical data outcomes were examined using chi-square tests or Fisher's Exact probabilities (for 2x2 tables with an expected cell size less than 5).

Treatment groups were compared at each measurement point for potential confounders to treatment effect, including age, natural healing (mean number of days from baseline), medical therapy compliance (mean Compliance Score and percentage of recruits reporting "high compliance"), duration of symptoms at baseline, baseline injury severity, activity level in days preceding measurements (ITBS disability days), and medication use in days preceding measurements. Continuous data were compared using *t* tests; categorical data using chi-square

tests or Fisher's Exact probabilities. There were no differences between the groups on any confounders except medical therapy compliance.

One-tailed tests of significance were used for interpretation of LLLT efficacy with the following justifications: the FDA has categorized LLLT devices for pain treatment as nonsignificant risk devices;[39] LLLT technology has been used in other countries for decades without reports of significant adverse effects; and, to the authors' knowledge, no published reports show that LLLT applied within the operating parameters used in this study has a negative effect on clinical outcome. Two-tailed tests of significance were used to interpret statistical analyses of potential confounders and analyses of the reliability and validity of efficacy measurements.

Power calculations were performed for the primary efficacy endpoints and were based on the effect size for *t*-test comparisons of group means for one-tailed tests with a significance level of .05. The per protocol sample of 42 was estimated to have at least a 33% power to detect a difference of 6 points in mean KVQ score, assuming a SD of 16 points, and at least a 49% power to detect a difference of 0.5 points in mean SICR, assuming a SD of 0.98 points. All analyses were performed using SPSS PC version 10.

RESULTS

Sample

The disposition of trial participants is shown in Figure 1. A total of 55 USMC male recruits were enrolled in the trial. Twenty-six were randomized to the LLLT group and 29 to the Placebo group. One recruit in the Placebo group was discharged from the USMC for reasons unrelated to ITBS after one LLLT session and was lost to follow-up. He was excluded from all analyses. Another 12 recruits (5 LLLT and 7 Placebo) were diagnosed during the course of the study with severe other injuries or illnesses that required training cessation and referral to MRP. In the LLLT group, other medical conditions included pneumonia, low back pain, tibia stress fracture, meniscal tear, and knee sprains and strains; in the Placebo group, liver disorder, fractured ankle, shoulder dislocation, calcaneal stress fractures, ITBS contralateral leg, and knee sprains and strains. Because these other medical conditions and the recruits' removal from physical training were significant confounders to the assessment of LLLT effectiveness, the 12 MRP recruits were excluded from analyses. The per protocol analysis sample consisted of 42 recruits, 22 in the LLLT and 20 in the Placebo group. At study enrollment, the LLLT and Placebo groups were similar in participant demographics and ITBS clinical characteristics (Table 1). In the LLLT group 63.6% (n = 14) of recruits were Caucasian, 27.3% (n = 6) Hispanic, and 9.1% (n = 2) African-American; in the Placebo group 50.0% (n = 10) were Caucasian, 40.0% Hispanic (n = 8), 5.0% (n = 1) African-American, and 5.0% (n = 1) Native American.

Figure 1: Profile of Randomized Controlled Trial (Insert Figure 1 here)

Table 1. Comparison of Demographic and Baseline ITBS Clinical Characteristics Between Treatment Groups (Insert Table 1 here)

Primary Efficacy Outcomes

Adjusted mean KVQ Scores for the groups are compared in Figure 2. The graph demonstrates the anticipated pattern of an early accelerated improvement in ITBS symptoms in the LLLT group relative to the Placebo group. At treatment session 2, after only one laser treatment, the LLLT group had a 21.7% greater reduction in mean KVQ Score than did the Placebo group (34.66 vs. 44.24, $P = 0.047$), with a mean score within the mild pain and disability range (10 to 40) while the Placebo mean KVQ Score was still within the moderate range (> 40 to 70).

Figure 2. Adjusted Mean ITBS Pain and Disability Score (KVQ Score) at Each Treatment Session (Insert Figure 2 here)

The percent of recruits in each treatment group who showed a 30% or greater reduction from baseline in KVQ Score is presented in Figure 3. The results mirrored those of the mean KVQ, showing an early accelerated improvement in ITBS symptoms in the LLLT group, followed by a disappearance in group differences. At treatment session 2, the LLLT group had 32.2% more recruits with at least a 30% reduction in ITBS pain and disability than did the Placebo group (77.3% [n=17] vs. 45% [n=9], $P = .016$).

Figure 3. Proportion of Recruits With 30% or Greater Reduction From Baseline in ITBS Pain and Disability (KVQ Score) at Each Treatment Session (Insert Figure 3 here)

There were no significant differences between the treatment groups in percent of recruits with at least a 50% reduction from baseline in KVQ Score; however results showed the same pattern of the greatest difference between the groups at treatment session 2 (50% [n = 11] of LLLT compared with 35% of Placebo recruits [n=7], $P = .164$).

Figure 4 presents the adjusted mean SICR by group at each treatment session. At day 7, the mean reported SICR for the LLLT was 23.1% higher than for the Placebo group (3.2, between "better" and "much better" compared to 2.6, between "no change" and "better, " ($P = .009$). Mean SICR was similar for the groups during treatment week 2 until day 14 when the LLLT group again reported greater symptom improvement (3.50 vs. 3.00, $P = .041$).

Figure 4. Adjusted Mean Symptom Improvement Category Rating (SICR) at Each Treatment Session (Insert Figure 4 here)

The percent of recruits in each group who reported some ITBS symptom improvement (since previous treatment session) at each treatment session are presented in Figure 5. At every measurement point, a higher percentage of LLLT group recruits reported symptom improvement, and the differences between the groups were statistically significant at day 7 and at day 14. After 1 week of treatment, 95% (n = 21) of the LLLT recruits compared to only 55% (n = 11) of the

Placebo recruits reported symptom improvement ($P = .003$). At the end of the second treatment week, 90.9% (n = 20) of the LLLT recruits compared to 65% (n = 13) of the Placebo recruits reported symptom improvement ($P = .047$).

Figure 5. Proportion of Recruits Reporting Symptom Improvement at Each Treatment Session

(Insert Figure 5 here)

Compliance With Medical Therapy

The LLLT group had lower mean compliance scores than the Placebo group at every measurement session, and the mean differences were significant at each of the second week measurements: session 4/day 7 (67% vs. 78%, $P = .033$), session 5 (65% vs. 78%, $P = .014$), session 6 (61% vs. 80%, $P = .007$), and day 14 (59% vs. 79%, $P = .004$). The Placebo group maintained an overall compliance of 78% to 80% throughout the 2-week treatment phase, while the LLLT group had a maximum compliance of 71% at treatment session 2 that steadily dropped to a low of 59% on day 14.

For compliance on the four individual components of the medical therapy regimen (naproxen use, icing, stretching, light duty), the LLLT group was significantly less likely than the Placebo group to be highly compliant with naproxen use and icing. For both naproxen use and icing compliance, group differences gradually increased and became statistically significant during treatment week 2. Ninety-five to 100% of Placebo recruits reported high compliance with naproxen use at each treatment session, while the percent of highly compliant LLLT recruits steadily dropped from a high of 86% at treatment session 3 to a low of 68% on day 14 (Figure 6).

At least 30% of Placebo recruits reported high compliance with icing at each treatment session while the percent of highly compliant LLLT recruits steadily dropped from a high of 23% at session 2 to consistently less than 10% from day 7 onward (Figure 7).

Figure 6. Proportion of Recruits Highly Compliant With Naproxen Use in Days Since Prior Treatment Session (Insert Figure 6 here)

Figure 7. Proportion of Recruits Highly Compliant With Icing in Days Since Prior Treatment Session (Insert Figure 7 here)

Secondary Efficacy Outcomes

The mean reported days of medication use and the mean reported days of ITBS disability during the treatment period, the follow-up period, and over the course of the study were similar for both treatment groups.

The number of recruits who reported CISG 1 (injury resolution, no pain or disability even with extreme physical exertion) after one week of treatment was very low for each group (LLLT =0, Placebo=2), and the difference was not statistically significant. At the completion of the 2-week treatment period, more than twice as many recruits in the LLLT group (36.4% vs. 15.0%) reported CISG 1, a difference that was nearly statistically significant ($P = .058$).

Durability of Treatment Effect

At the completion of the treatment phase, a total of 63.6% of the LLLT recruits (n = 7 partial and 7 full) and 60.0% of the Placebo recruits (n = 9 partial and 3 full) met the criteria for either

partial or full ITBS recovery. Of the recruits with partial recoveries, 100% in the LLLT group (n = 7) and 88.9% in the Placebo group (n = 8) reported a durable effect. Of the recruits with full recoveries, 6 LLLT (85.7%) compared to only 1 Placebo (33.3%) reported a durable effect, although the difference was not statistically significant.

Safety

There were no significant adverse events reported during this trial.

COMMENT

The results of this study demonstrated that LLLT, used in conjunction with standard conservative medical therapy, was more efficacious than conservative medical therapy alone in reducing the pain and functional disability associated with acute exercise-induced ITBS in young adult men. The LLLT and conservative medical therapy group resulted in an early accelerated reduction in subjective ITBS pain and disability and an overall milder clinical course when compared to conservative medical therapy alone. The treatment effect was durable to 4 weeks post treatment, even when the participants returned to full strenuous physical activity. The study results further suggest that LLLT may reduce the medication requirements for the treatment of ITBS. There were no adverse events reported in this study, providing additional evidence for the safety of LLLT.

As hypothesized, the greatest differences between treatment groups and ITBS symptom resolution occurred during the first treatment week, after which symptoms in the Placebo group decreased to near those of the LLLT group as was expected with medical therapy and natural healing in a young, healthy population. After only one laser treatment, the LLLT group showed a 21.7% greater reduction in mean ITBS pain and disability than did the Placebo group, reporting only mild symptoms while the Placebo group reported moderate symptoms. Additionally, at treatment session 2 there were 32.2% more recruits in the LLLT group with at least a 30% reduction in ITBS pain and disability than in the Placebo group (77.3% vs. 45%). Although the KVQ Scores in both groups were similar and within the mild range by treatment session 3, the SICR and CISG measurements detected more subtle clinical differences between the groups in

degree of the healing response and indicated that the LLLT recruits continued to experience an overall milder clinical course and a more rapid resolution of symptoms. At the completion of the first treatment week (after 3 LLLT sessions), nearly twice as many LLLT recruits as Placebo recruits (95% vs. 55%) reported continued symptom improvement, and the mean SICR for the LLLT group was 23.1% higher than that for the Placebo group. At the completion of the second week of treatment (after all 6 LLLT sessions), 90.9% of LLLT recruits compared to 65% of Placebo recruits reported symptom improvement, and the mean SICR was 16.7% higher for the LLLT group. Additionally, at the completion of the second treatment week, more than twice as many recruits in the LLLT group (36.4% vs. 15.0%, $P = .058$) reported CISG 1 (resolved). The LLLT group's consistently lower medical therapy compliance scores during the second treatment week provided further indirect evidence of the continued accelerated healing stimulated by the laser since reduced compliance with medical therapy is typical behavior for patients with resolving musculoskeletal injuries. Additionally, the lower compliance with naproxen use among the LLLT group suggested that the recruits were taking these medications at lower doses during the second treatment week, and that LLLT may result in reduced medication requirements for acute tendinitis management.

Although continued enhanced ITBS symptom improvement in the LLLT group relative to the Placebo group late in the second treatment week was not anticipated, the study findings are consistent with the pathophysiology of tendon injury and healing and with the proposed mechanism of action for LLLT. ITBS is an overuse tendinitis, an injury in which microscopic tears in the tendon fibrils are caused by repetitive stress.[9] MRI studies of ITBS[31] and animal models simulating tendon repetitive overload injury[40,41] indicate that both inflammatory and

degenerative changes occur in the injured tendon. Research using severed tendon models show that an inflammatory stage of healing occurs during the first 6 days, followed by a fibroblastic proliferation stage at days 5 through 21, and a tendon remodeling stage at days 20 onward.[9,30] LLLT has been shown to decrease edema and inflammation[13,18,42-44] and to promote fibroblast synthesis of collagen and glucosaminoglycans,[13,15,16,18,43,45,46] compounds that comprise part of the tendon ground substance. Therefore it is believed to exert a therapeutic effect in tendon healing during both the inflammatory and proliferative stages. The results of this study are consistent with this theory, with the accelerated resolution of ITBS pain and disability in the LLLT group seen during the first treatment week suggestive of an LLLT effect on inflammation, and the greater symptom improvement reported by the laser group at the end of the second week suggestive of an LLLT effect on collagen proliferation.

Comparisons of our study results with those of other LLLT clinical efficacy trials for musculoskeletal injuries are complicated by differences in outcome measurements and injuries treated, and by variabilities in LLLT device technical characteristics, application techniques, and operating parameters. However, investigations of LLLT treatment efficacy in tendinopathies, in which the application techniques and LLLT device operating parameters were broadly similar to those used in this study, have shown results comparable to ours with a weighted mean difference in treatment effect of 22.1% in favor of LLLT over placebo.[17] Although some prior LLLT clinical efficacy trials for tendinopathies have shown no difference between laser and placebo, these studies have been criticized for methodological errors and/or suboptimal laser dosing or application procedures.[17,21]

Potential limitations to this study were the small sample size and the inclusion of only young, healthy adult men. However, because of the etiology of the injury treated, and the unique diverse composition of the USMC recruit population, the results are generalizable to the intended target population. Exercise-induced acute tendinitis, and specifically ITBS, generally is associated with the performance of vigorous exercise; and the vast majority of Americans who engage in vigorous physical activity are young, healthy adults,[47,48] aged 18 to 29 years.[47] The study sample was representative of the American young adult male population, with recruits from a variety of backgrounds, races, and geographic locations including 17 different states. Although no women were included in the study, there is no evidence to suggest that the clinical response to tendinitis treatment modalities differ between the sexes.[9] Likewise, prior LLLT studies that have included women provide no evidence of treatment effect differences between the sexes.[23,26,49-51] Although the generalizability of the results to an older population is less clear, assuming the tendon healing mechanism remains the same, it is reasonable to expect a beneficial LLLT effect. The study finding that LLLT accelerated healing in a young, healthy population with a vigorous natural healing response, concurrently treated with an effective medical regimen, suggests that the LLLT therapeutic effect may be even greater in an older population with a slower natural healing process.

In summary, this was the first study to demonstrate the efficacy of LLLT as an adjunct to standard conservative medical therapy in the treatment of an exercise-induced acute tendinitis in healthy, young physically active men. The accelerated resolution of pain and functional disability occurred early, after only one laser treatment. The rapid onset of LLLT stimulated effects may have important clinical and fiscal implications for athletes returning to play and individuals returning to physically demanding occupations or military duties. The FDA has recently made

LLLT available for therapeutic use in the United States. Although much research on the clinical effects and optimal applications of LLLT is still needed, this study demonstrated that this new modality may play a significant role in the future management of sports- and exercise-induced musculoskeletal injuries.

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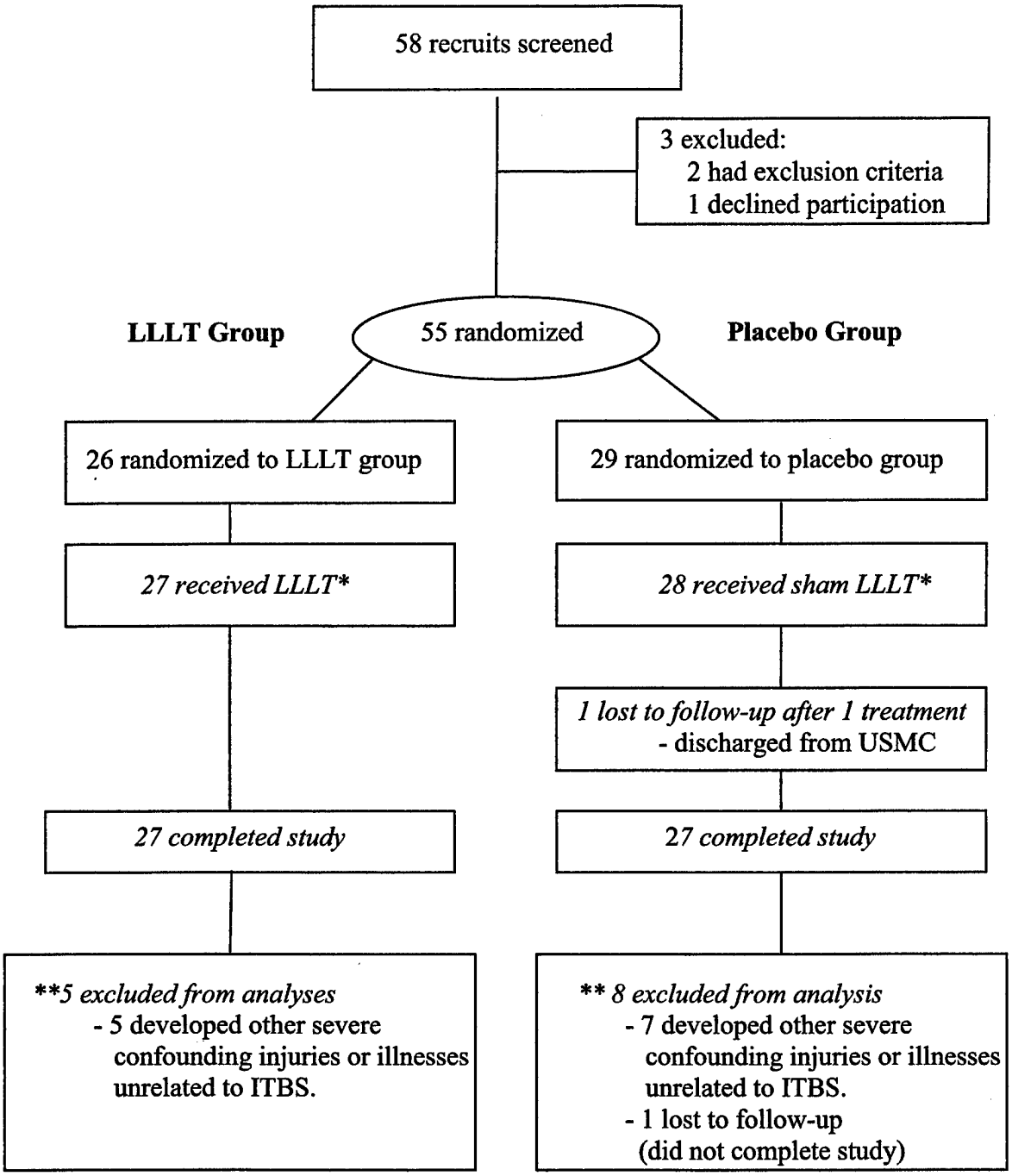
Figure 1: Disposition of Study Participants

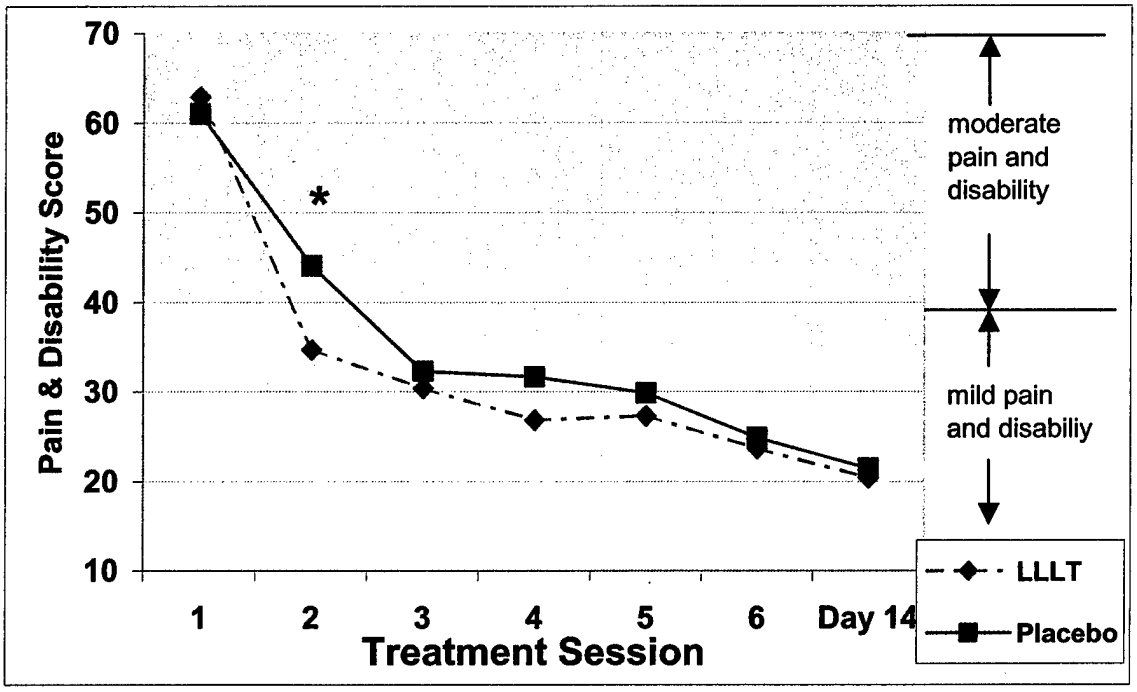


* One Recruit randomized to placebo group was erroneously administered active LLLT at 2nd treatment session and was crossed over to LLLT group (treated and analyzed in LLLT group).

** See Results section of manuscript

Figure 2. Adjusted Mean ITBS Pain and Disability Score (KVQ Score)

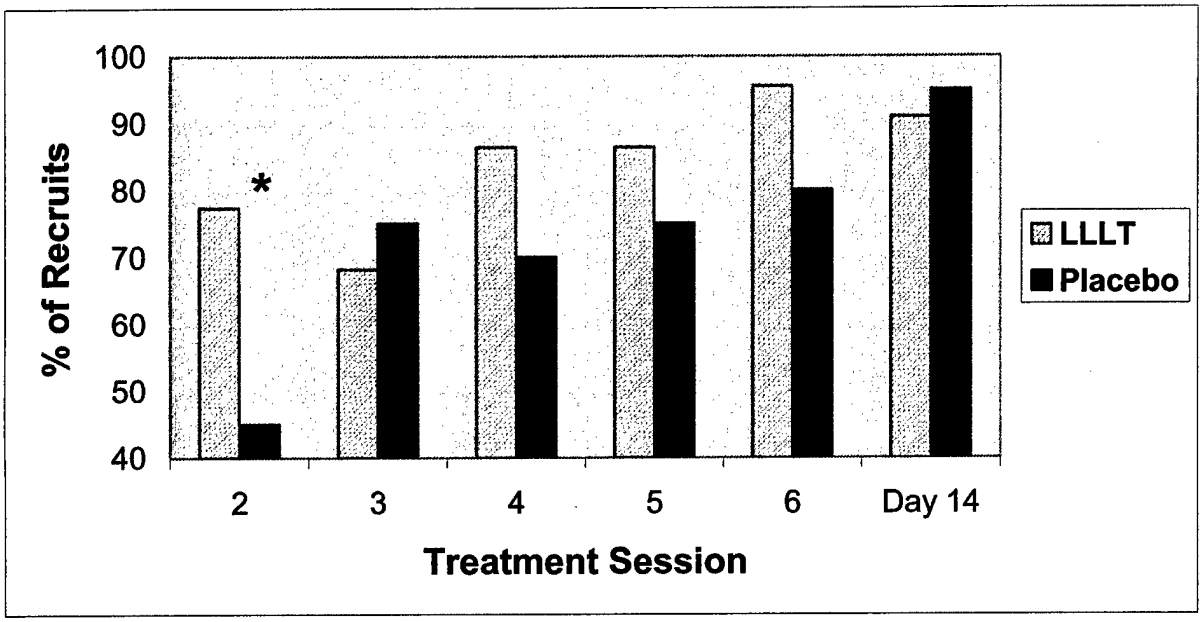
at Each Treatment Session



*treatment 2: $P = .047$

Treatment session 4 = study day 7

Figure 3. Proportion of Recruits With 30% or Greater Reduction From Baseline in ITBS Pain and Disability (KVQ Score) at Each Treatment Session

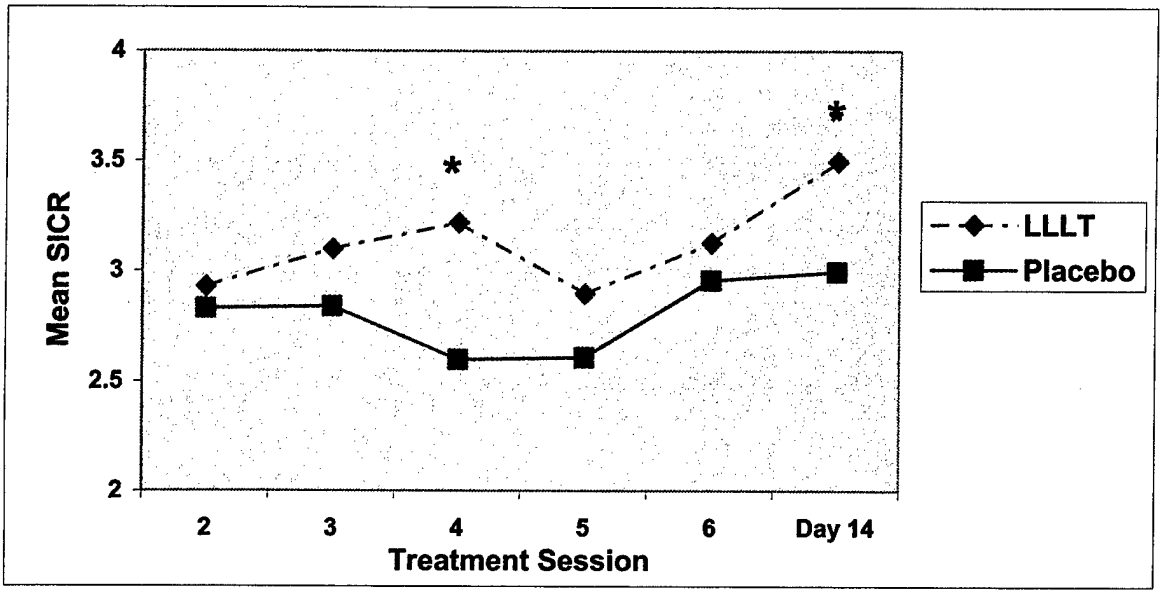


*treatment 2: $P = .016$

Treatment session 4 = study day 7

Figure 4. Adjusted Mean Symptom Improvement Category Rating (SICR)

at Each Treatment session

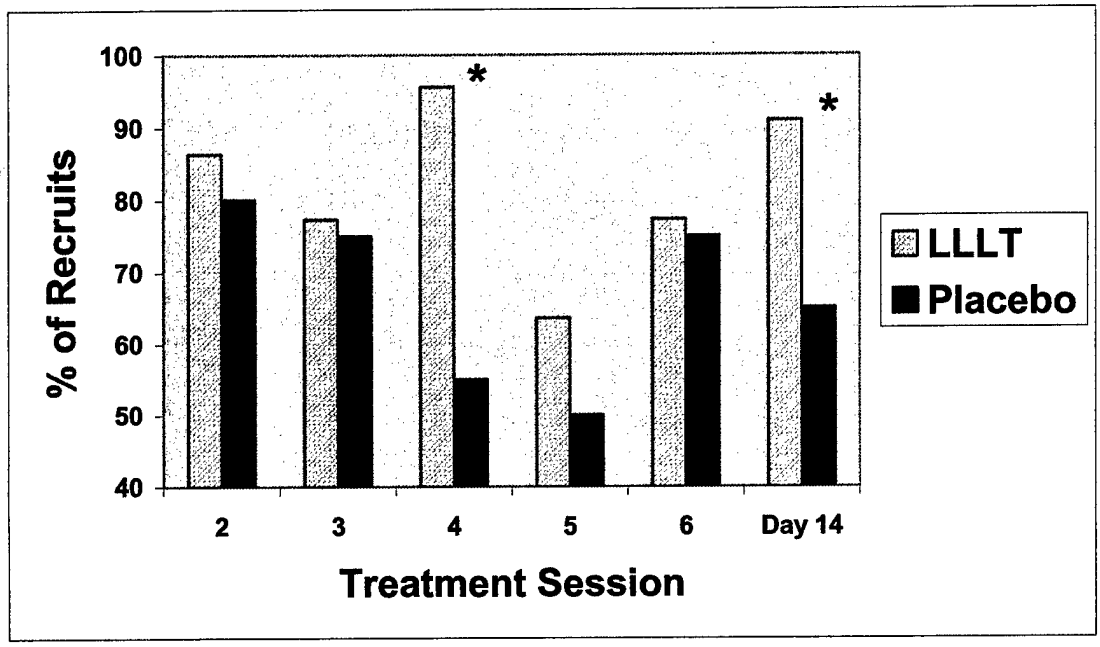


*treatment 4 (day 7): $P = .009$, day 14: $P = .041$

SICR: 2 = no change, 3 = better, 4 = much better

Treatment session 4 = study day 7

Figure 5. Proportion of Recruits Reporting Symptom Improvement at Each Treatment Session

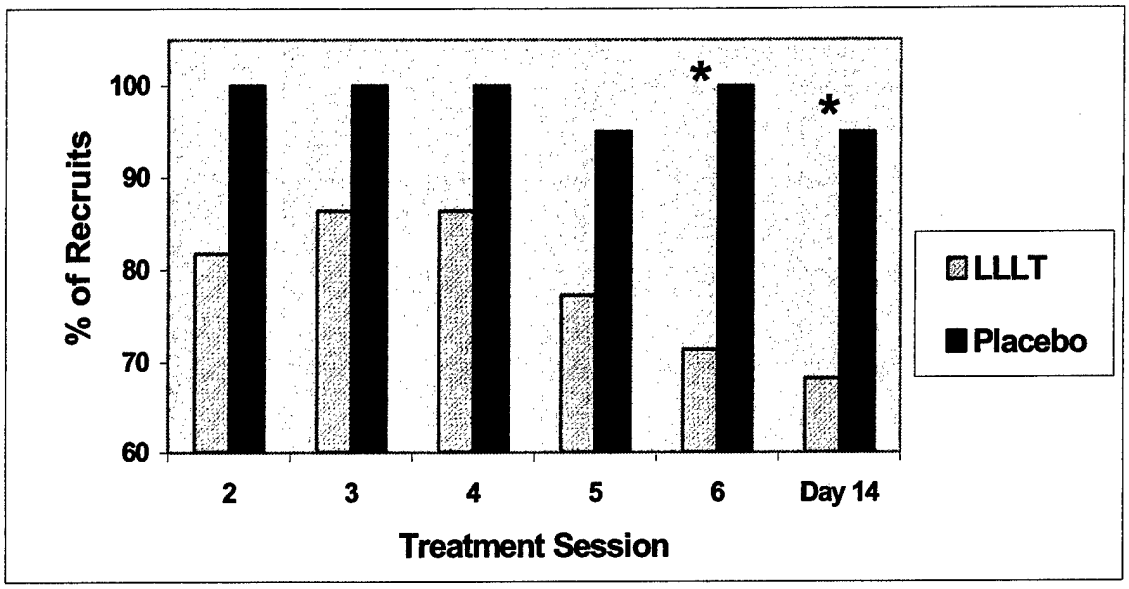


*Treatment 4: $P = .003$; day 14: $P = .047$

Symptom Improvement = SICR responses of better, much better, or resolved and is relative to symptoms at previous treatment session.

Treatment session 4 = study day 7

Figure 6. Proportion of Recruits Highly Compliant With Naproxen Use in Days Since Prior Treatment Session



* treatment 6: $P = .021$; day 14: $P = .047$

Treatment session 4 = study day 7

Table 1. Comparison of Demographic and Baseline ITBS Clinical Characteristics Between Treatment Groups

	LLLT			Placebo				
	Mean	Standard Deviation	Range	Mean	Standard Deviation	Range	*t* test	Sig* (2-tail)
Age (y)	19.73	2.33	17-26	20.40	1.90	18-24	-1.0	0.315
Days of symptoms	4.14	2.26	1-9	4.26	3.14	1-13	-0.14	0.889
Days in training	6.79	3.84	1-14	6.74	4.27	2-18	0.04	0.968
KVQ Score	62.94	14.39	35.91-93.29	61.01	13.76	34.72-77.32	0.44	0.660
Clinical Injury Severity Grade (CISG)	4.64	1.00	3-6	4.45	1.00	2-6	0.60	0.550

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14. ABSTRACT (maximum 200 words)

The efficacy of low-level laser therapy for the treatment of acute iliotibial band syndrome was evaluated in a sample of Marine Corps recruits. A randomized, placebo-controlled, double-blind trial was conducted with 22 recruits receiving an active laser treatment, and 20 recruits receiving a placebo/sham treatment. In addition to the laser/placebo treatment, all recruits received standard medical therapy consisting of naproxen, icing, stretching, and rest. The laser treatment consisted of 6 laser/placebo treatments, 3 per week for 2 weeks. All recruits were followed weekly for 4 weeks after conclusion of the laser/placebo treatments. After 1 treatment, the laser group showed a 21.7% greater reduction in mean pain/disability versus placebo (p=.047), and 32.2% more laser recruits had 30% or greater reduction in pain/disability (77.3% vs. 45%, p=.016). After 3 treatments, 95% of laser recruits compared to 55% of placebo (p=.003) reported symptom improvement, and the mean symptom improvement rating in the laser group was 23.1% higher (p=.009). After 6 treatments, 90.9% of laser recruits compared to 65% of placebo (p=.047) reported symptom improvement and the mean symptom improvement rating in the laser group was 16.7% higher (p=.041). This was the first study to demonstrate efficacy of low-level laser therapy as an adjunct to medical therapy for acute tendinitis. The data suggest that low-level laser therapy accelerates reductions in iliotibial band syndrome pain and disability in young healthy men.

15. SUBJECT TERMS
Low-level laser therapy, tendinitis, iliotibial band syndrome, military, randomized clinical trial, exercise

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